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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/617,067 | 07/10/2003 | David G. Beer | UM-08196 | 8445 |

7590 05/15/2006
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EXAMINER

SANG, HONG

ART UNIT PAPER NUMBER

1643

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-----------------------------|--|
| Office Action Summary | Application No. 10/617,067 | Applicant(s) BEER ET AL. | |
| | Examiner Hong Sang | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Beer et al.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, drawn in part to a method for characterizing lung tissue in a subject, comprising detecting a decreased or increased expressions relative to a non-cancerous lung tissue control of a marker, wherein said detecting the presence of expression of said marker comprises detecting the presence of mRNA corresponding to said marker, classified in class 435, subclass 6.

If applicants elect this group for prosecution on the merits, applicants are further required to elect a single marker from Claim 1 (i.e. AOE372, ATP5D, B4GALT, Ppase, GRP58, GSTM4, P4HB, TPI, and UCHL1). This election should not be construed as an election of species. This is a restriction requirement. Each of the marks is a structurally and functionally distinct molecule that would require separate search.
 - II. Claims 1-7, drawn in part to a method for characterizing lung tissue in a subject, comprising detecting a decreased or increased expressions relative to a non-cancerous lung tissue control of a marker, wherein said detecting the presence of expression of said marker comprises detecting the presence of a polypeptide corresponding to said marker, classified in class 435, subclass 7.1.

If applicants elect this group for prosecution on the merits, applicants are further required to elect a single marker from Claim 1 (i.e. AOE372, ATP5D, B4GALT, Ppase, GRP58, GSTM4, P4HB, TPI, and UCHL1). This election should not be construed as an election of species. This is a restriction requirement. Each of the marks is a structurally and functionally distinct molecule that would require separate search.

- III. Claims 8-10, drawn to a method of characterizing lung cancer, comprising detecting the level of expression relative to a non-cancerous lung tissue control of a marker, classified in class 435, subclass 6.

If applicants elect this group for prosecution on the merits, applicants are further required to elect a single marker from Claim 8 (i.e. GRP58, PSMC, VIM, SOD, and TPI). This election should not be construed as an election of species. This is a restriction requirement. Each of the marks is a structurally and functionally distinct molecule that would require separate search.

- IV. Claims 11-12, drawn to a method of predicting survival in lung cancer patients, comprising detecting the presence or absence of a marker, classified in class 435, subclass 4.
- V. Claims 13-14, drawn to a lung cancer expression profile map comprising gene expression level information for two or more markers, classified in class 702, subclass 19, for example.

If applicants elect this group for prosecution on the merits, applicants are further required to elect two markers from Claim 13. This election should not be construed as an election of species. This is a restriction requirement. Each of the marks is structurally and functionally distinct molecule that would require separate search.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method for characterizing lung tissue in a subject (groups I-II), a method for characterizing lung cancer (group III), and the a method of predicting survival in lung cancer patients (group IV) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. For groups I and II, a lung tissue from any subject is characterized; for group III, a lung cancer is characterized; and for group IV, the survival of a lung cancer patients is predicted. Therefore, each group has different functions or different effects. Moreover, each invention performs this function using a structurally and functionally divergent material. The markers used in each group are distinct. Groups I and II further differ from each other in that mRNA is detected in group I, whereas, polypeptide is detected in group II. The assays used for detecting an mRNA and a polypeptide are distinct. For these reasons the Inventions I-IV are patentably distinct. Furthermore, the

distinct steps and products require separate and distinct searches. Searching for inventions I-IV is not coextensive. As such, it would be burdensome to search the inventions of groups I-IV together.

Group V and any one of groups I-IV are unrelated as the product of group V is not used or otherwise involved in the process of groups I-IV.

3. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. This application contains claims (see claim 11) directed to the following patentably distinct species: CK19, CK7 and CK8. The species are independent or distinct because they are all structurally and functionally distinct molecules, which would require separate searches.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Art Unit: 1643

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang
Art Unit 1643
Apr. 28, 2006



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER